



MEDICAL INDUSTRIES AMERICA INC.

2879 R AVENUE
ADEL, IOWA
U.S.A. 50003-8055

TEL. (515) 993-5001
1-800-759-3038
FAX (515) 993-4172

K964078
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ENCLOSURE 'B'

EXECUTIVE SUMMARY OF THE MODEL 3050 "SPORT-NEB"

The model 3050 "Sport-Neb" is a small air compressor designed to provide sufficient air pressure and flow to power a hand held nebulizer such as the Salter #8900.

Nebulizer compressors are very basic devices comprising of a motor compressor assembly, wiring, switch, power cord and case. Nebulizer compressors have been on the market for many years. "Medical Industries America, Inc." is currently marketing two other nebulizer compressors - the "Aerosol Two" and the "AEROMAX". The "Sport-Neb" is virtually the same as the "AEROMAX" with the exception of the case which is smaller and more portable.

DEVICE DESCRIPTION:

The Model 3050 "sport-Neb" is a small, lightweight, nebulizer compressor. It measures 7 1/2" X 7 1/2" X 4 1/2". The housing is grey in color and moulded from ABS plastic. External components include a switch, filter housing, AC cord and the air outlet barb. An optional carry bag will be offered to store the patients hand held nebulizer.

The handle is built into the housing

The operating components are located internally. The compressor, some minor wiring and the exhaust/intake plumbing are located inside.

MODIFICATIONS:

At this time, there are no intentions to modify the device.



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ENCLOSURE 'B'

EXECUTIVE SUMMARY OF THE MODEL 3050 "SPORT-NEB"
COMPRESSOR (CONTINUED)

DESCRIPTION OF THE MODEL 3002 "AEROMAX" (PREDICATE DEVICE)

The Model 3002 "AEROMAX" manufactured by "Medical Industries America, Inc. is also a small, lightweight nebulizer compressor. It measures approximately 12 X 8 1/2 X 4 1/2. It is grey in color.

In the front of the device is the lid. Under the lid are the following components - switch, AC cord, filter housing and air outlet barb.

The "AEROMAX" has the operating components located internally also. The compressor, the intake/exhaust plumbing and the wiring system are located here.

INTENDED USE:

The Model 3002 "AEROMAX" has the same intended use as the Model 3050.